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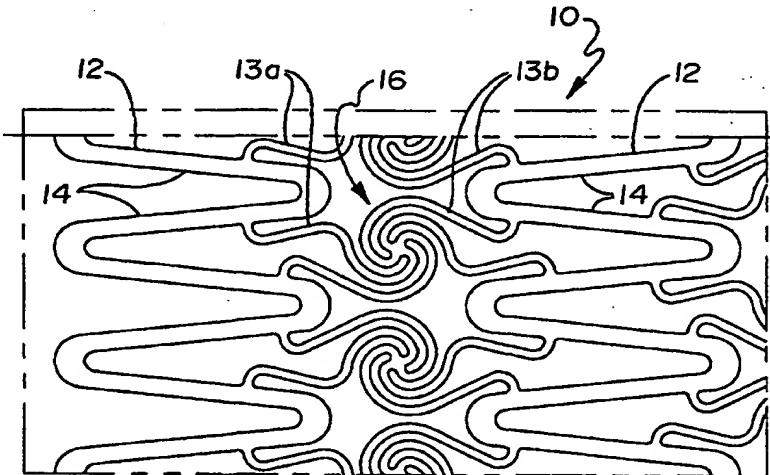
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(54) Title: IMPROVED STENT CONFIGURATIONS



(57) Abstract

A stent includes a coil or coil-like structure comprised of joined elements which are coiled or bent and which unwind, uncoil or unbend to a more or less straightened condition on expansion of the stent. These structures provide regions of low strain in the stent during expansion. These elements may be joined to each other or to any radially expansive members of any kind, annular serpentine members being preferred.

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IMPROVED STENT CONFIGURATIONS

BACKGROUND OF THE INVENTION

1. Field of the Invention

5 This invention relates to stents of improved configuration which incorporate coiled articulations which unwind to form bracing structures or scaffolding upon expansion.

2. Brief Description of the Prior Art

10 Stents are radially expandable endoprostheses which are typically intravascular implants capable of being implanted transluminally and enlarged radially after being introduced percutaneously. They have also been implanted in urinary tracts and bile ducts. They are used to reinforce body vessels and to prevent restenosis following angioplasty in the vascular system. They may be self-expanding
15 or expanded by an internal radial force, such as when mounted on a balloon.

In the past, stents have assumed many configurations and been made of many materials, including metals and plastic. Ordinary metals such as stainless steel have been used as have shape memory metals such as nitinol and the like. Stents have also been made of biodegradable plastic materials. They have been formed from wire,
20 tube stock, etc.

SUMMARY OF THE INVENTION

This invention provides a new configuration for stents which may be adapted by all of the various types of prior art stents referred to hereinabove. There
25 are numerous advantages to the new configuration. It limits recoil and adds resistance to compression for the expanded stent, among other things. It is longitudinally flexible in both the unexpanded and expanded conditions. It has several embodiments.

An important part of the new configuration includes a coil or coil-like structure comprised of joined elements which are coiled or bent and which unwind,
30 uncoil or unbend to a more or less straightened condition on expansion of the stent. Such structures are hereinafter referred to collectively as coils, spirals or coil-like structures. These structures provide regions of low strain in the stent during

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expansion. These elements may be joined to each other or to any radially expansive members of any kind, annular serpentine members being preferred.

Brief Description of the Figures

5 Figure 1 is a flat view of one pattern embodiment of a stent configuration of the invention (unexpanded);
Figure 2 is a detail of a portion of Figure 1;
Figure 3 is an end view of a stent of the Figure 1 pattern according to the invention showing it in tubular configuration;

10 Figure 4 is a showing of a stent in the embodiment of the preceding Figures in perspective and in an unexpanded configuration;
Figure 5 is a showing of the stent of Figure 4 fully expanded with details of the front and rear of the stent;
Figures 6, 7 and 8 are showings of the stent of Figure 4 in various
15 stages of expansion with only details of the front of the stent shown for simplicity;
Figure 9 is a plan view showing another embodiment of the invention;
Figure 10 is a showing of a modified embodiment;
Figure 11 is a showing of another embodiment;
Figure 12 is a detail of a portion of Figure 11;

20 Figure 13 is a showing of the stent of Figures 11 and 12 in an expanded configuration;
Figure 14 is a showing of another embodiment;
Figure 15 is a showing of still another embodiment;
Figure 16 is a showing of yet another embodiment;

25 Figure 17 is a showing of still another embodiment;
Figures 18-28 show various coil-like arrangements of the invention;
Figure 29 shows another embodiment of the invention;
Figure 30 shows yet another embodiment; and
Figure 31 shows still another embodiment of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

One preferred embodiment of the invention is illustrated in Figures 1-8.

It comprises a metal tube-like structure 10 as best shown in Figures 3 and 4, such as nitinol or stainless steel, which has been etched or laser cut to the configuration shown
5 in the plan view of Figures 1 and 2 and in a short version as shown in Figure 4. The configuration is made up of a series of serpentine annular expandable elements or segments 12 which form loops 14 to allow for radial annular expansion. Segments 12 may be other configurations but serpentine is preferred. Elements 12 are interconnected by pairs of elongated members 13a and 13b which are attached at one
10 end to successive loops 14 of a segment 12 and which are joined at their other ends to adjacent pairs of elongated members 13a and 13b, as best seen in detail in Figure 2. Members 13a and 13b are preferably of narrower gauge than members 12 and are joined together in a coiled or spiral arrangement as shown generally at 16. Spiral 16 forms a structure about which members 13 may uncoil or unwind in a
15 counterclockwise direction or clockwise direction to a substantially straight condition, depending on the spiral winding direction, upon radial expansion of members 12. In this embodiment spirals 16 are formed in alternate wound structures so that some unwind in one direction and some in the other direction. Of course, in any embodiment the spirals can be formed so that they all unwind in one direction, either
20 clockwise or counterclockwise and they may have more or fewer members 13. Also, more or less spirals may be included between the segments. The uncoiling is accompanied by a straightening action with respect to members 13 as is described in more detail in connection with Figures 4-8. It can be seen from Figures 4 through 8 that the resultant configuration in an expanded stent of this configuration is comprised
25 of a plurality of cells, the perimeter of each of which is defined by a pair of members or struts defined by the loop portion 14 of segment 12 and a pair of members or struts 13. The cells are joined at 16 as best seen in Figure 8. More specifically the cells are of two kinds as shown in Figure 8. A first pair of cells are A and B made up of a segment 12 and two struts 13a for cell A or 13b for cell B. A second pair of cells are
30 C and D made up of an inward loop portion 14 of segment 12 and a strut 13a and a strut 13b for cells C and D.

When a stent of the invention, such as that shown in Figures 1-4 undergoes expansion, such as from the embodiment of Figure 4, it will appear as shown in Figure 5 in the fully expanded condition. Figure 5 shows the stent in perspective.

5 The unwinding action which the coil elements 16 undergo upon stent expansion is best seen in Figures 6-8 which show only the front side surface of the stent for simplicity and clarity.

As radial expansion begins (seen in Figure 6) it can be appreciated that the coil elements 16 undergo an unwinding or straightening action by a pulling force 10 on all of the members 13. Specifically, as expansion occurs, elements 13 undergo a straightening action as can be seen in the early stages of expansion in Figure 6.

Upon further expansion (seen in Figure 7), spirals 16 undergo further unwinding, i.e., elements 13 undergo further straightening.

Finally in Figure 8, substantial full expansion provides substantially 15 straightened elements 13 which in that condition limit stent recoil and increase the resistance to compression of the stent.

Figure 9 shows a modified embodiment in which elements 13a and 13b contact segment 12 at the end of its loops 14. Also note in this embodiment that the coils 16 are all wound in the same direction.

20 Figure 10 shows an embodiment of the invention in which the spiral members 13 are more bent and less curvilinear but still form a coil-like configuration 16. The remainder of the configuration is similar to that of Figure 9. In Figure 10, elongate members 13 are shown prior to expansion of the stent. When the stent is expanded, members 13 unwind counter-clockwise and straighten somewhat. At full 25 expansion members 13 straighten still further and straighten substantially so as to provide resistance to compression of the stent and low recoil. The expanded configuration displays a cell configuration similar to that seen in Figure 8.

Other embodiments are shown in subsequent Figures with different coil arrangements. For example, the embodiment of Figures 11-13 shows coiled 30 arrangements 16 which are wound in the same direction and elements 13 attached at the end of loops 14 while some adjacent coils between segments are interconnected by members 15.

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Figure 14 shows some elements 13 in a spiral 16 contacting the end of loops 14 and some contacting segment 12 proper. Also, some adjacent coils are interconnected by members 17.

Figure 15 shows a flattened or elongated coil arrangement 16 and 5 elements 12 are angled with respect to the longitudinal axis of the stent. In previous embodiments, these elements or segments have been arranged parallel to the axis or horizontal. Elongated spirals as in Figure 13 and coils of previous Figures may be mixed together. (Not shown).

In the embodiments already discussed, annular expandable segments 10 such as segments 12 are interspersed with coil arrangements 16. However, as can be seen in Figure 16, at least a substantial portion or all of the stent body can be merely comprised of spiral arrangements 16 connected to each other. Actually, all of the body may consist of spirals. In this embodiment, the elements 13 interconnect between spirals over substantially the entire body of the stent. Optionally, the ends 15 may include segments 12 as shown.

The embodiment shown in Figure 17 shows segments 12 alternately angled in opposite directions and with legs thereof of different length and elements 13 contacting the segments at different locations, i.e., as at the loop portion 14 and at the segment portion proper.

20 Figures 18-28 demonstrate examples of what is meant by the terms coil, spiral and coil-like herein. Of course, additional members may be included in the coils.

Figure 29 shows segments 12 in a configuration other than the annular serpentine configuration of previous Figures.

25 Figure 30 shows alternate segments 12 in serpentine annular configuration interconnected by double rows of interconnected coil configurations 16.

Figure 31 is included to demonstrate that coils 16 may be included on the ends of a stent 10.

While this invention may be embodied in many different forms, there 30 are described in detail herein specific preferred embodiments of the invention. This description is an exemplification of the principles of the invention and is not intended to limit the invention to the particular embodiments illustrated.

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The above Examples and disclosure are intended to be illustrative and not exhaustive. These examples and description will suggest many variations and alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the attached claims. Those familiar
5 with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims attached hereto.

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What is claimed is as follows:

1. An expandable stent in the form of a generally tubular body including as part of the configuration thereof a plurality of coiled elements included in the stent body.
- 5 2. The stent of claim 1 wherein the coiled elements are at the ends of the stent.
3. The stent of claim 1 in which at least some of the coiled elements are connected to each other.
4. The stent of claim 2 in which the stent body is comprised of
- 10 substantially all coiled elements interconnected to each other.
5. The stent of claim 1 in which at least some of the coiled elements are interconnected between other stent elements.
6. The stent of claim 5 wherein the other stent elements are annular serpentine elements.
- 15 7. The stent of claim 6 wherein the serpentine portions of the elements are longitudinally arranged with respect to the longitudinal axis of the stent.
8. The stent of claim 6 wherein the serpentine portions of the elements are angularly arranged with respect to the longitudinal axis of the stent.
9. A stent comprised of a plurality of interconnected expandable cells,
- 20 each cell comprised of plurality of joined struts to form a perimeter of each cell, two of which are adjacent and curvilinear and meet two similarly arranged struts of an adjoining cell to form a coil-like joint at the joined ends of each cell and on expansion of the stent, all struts of each cell undergo deformation and the joined areas undergo straightening whereby the two struts of each cell joining the joined areas undergo a
- 25 straightening action.
10. The stent of claim 9 wherein the straightening action is an unwinding action.
11. The stent of claim 9 wherein two of the struts, other than the two curvilinear struts, forming a cell are a portion of a serpentine annular element, a
- 30 plurality of which are in spaced arrangement.
12. A stent comprised of:

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a plurality of longitudinally aligned and expandable segments of generally cylindrical configuration, expansion enlarging the diameter of the segments; at least one connector element extending from a segment to join a corresponding element extending from an adjacent segment, the connectors forming a 5 coil-like configuration between the segments, the members straightening upon expansion of the adjoining segments.

13. The stent of claim 12 wherein there are a pair of connector elements extending from a segment to join a corresponding pair extending from an adjacent segment.

10 14. The stent of claim 12 wherein the straightening of the members is an unwinding action.

15. The stent of claim 12 wherein the aligned expandable stent elements are in the form of annular serpentine segments.

16. The stent of claim 15 wherein the serpentine portions of the elements 15 are longitudinally arranged with respect to the longitudinal axis of the stent.

17. The stent of claim 15 wherein the serpentine portions of the elements are angularly arranged with respect to the longitudinal axis of the stent.

18. A stent comprised of:
a plurality of expandable segments of generally cylindrical
20 configuration;
connector elements extending between the segments to join
corresponding elements extending from an adjacent segment, the connectors forming
at least one coiled configuration between the segments, the coils straightening upon
stent expansion.

25 19. The stent of claim 18 wherein the connectors form a plurality of coiled configurations between the segments.

20. The stent of claim 18 wherein the straightening involves unwinding of
the coils.

AMENDED CLAIMS

[received by the International Bureau on 1 October 1998 (01.10.98);
original claims 1-20 replaced by amended claims 1-20 (3 pages)]

1. An expandable stent in the form of a generally tubular body including as part of the configuration thereof a plurality of spiral elements included in the stent body.
2. The stent of claim 1 wherein the spiral elements are at the ends of the stent.
3. The stent of claim 1 in which at least some of the spiral elements are connected to each other.
4. The stent of claim 2 in which the stent body is comprised of substantially all spiral elements interconnected to each other.
5. The stent of claim 1 in which at least some of the spiral elements are interconnected between other stent elements.
6. The stent of claim 5 wherein the other stent elements are annular serpentine elements.
7. The stent of claim 6 wherein the serpentine portions of the elements are longitudinally arranged with respect to the longitudinal axis of the stent.
8. The stent of claim 6 wherein the serpentine portions of the elements are angularly arranged with respect to the longitudinal axis of the stent.
9. A stent comprised of a plurality of interconnected expandable cells, each cell comprised of plurality of joined struts to form a perimeter of each cell, two of which are adjacent and curvilinear and meet two similarly arranged struts of an adjoining cell to form a spiral-like joint at the joined ends of each cell and on expansion of the stent, all struts of each cell undergo deformation and the joined areas undergo straightening whereby the two struts of each cell joining the joined areas undergo a straightening action.
10. The stent of claim 9 wherein the straightening action is an unwinding action.

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11. The stent of claim 9 wherein two of the struts, other than the two curvilinear struts, forming a cell are a portion of a serpentine annular element, a plurality of which are in spaced arrangement.

12. A stent comprised of:
a plurality of longitudinally aligned and expandable segments of generally cylindrical configuration, expansion enlarging the diameter of the segments;
at least one connector element extending from a segment to join a corresponding element extending from an adjacent segment, the connectors forming a spiral-like configuration between the segments, the members straightening upon expansion of the adjoining segments.

13. The stent of claim 12 wherein there are a pair of connector elements extending from a segment to join a corresponding pair extending from an adjacent segment.

14. The stent of claim 12 wherein the straightening of the members is an unwinding action.

15. The stent of claim 12 wherein the aligned expandable stent elements are in the form of annular serpentine segments.

16. The stent of claim 15 wherein the serpentine portions of the elements are longitudinally arranged with respect to the longitudinal axis of the stent.

17. The stent of claim 15 wherein the serpentine portions of the elements are angularly arranged with respect to the longitudinal axis of the stent.

18. A stent comprised of:
a plurality of expandable segments of generally cylindrical configuration;
connector elements extending between the segments to join corresponding

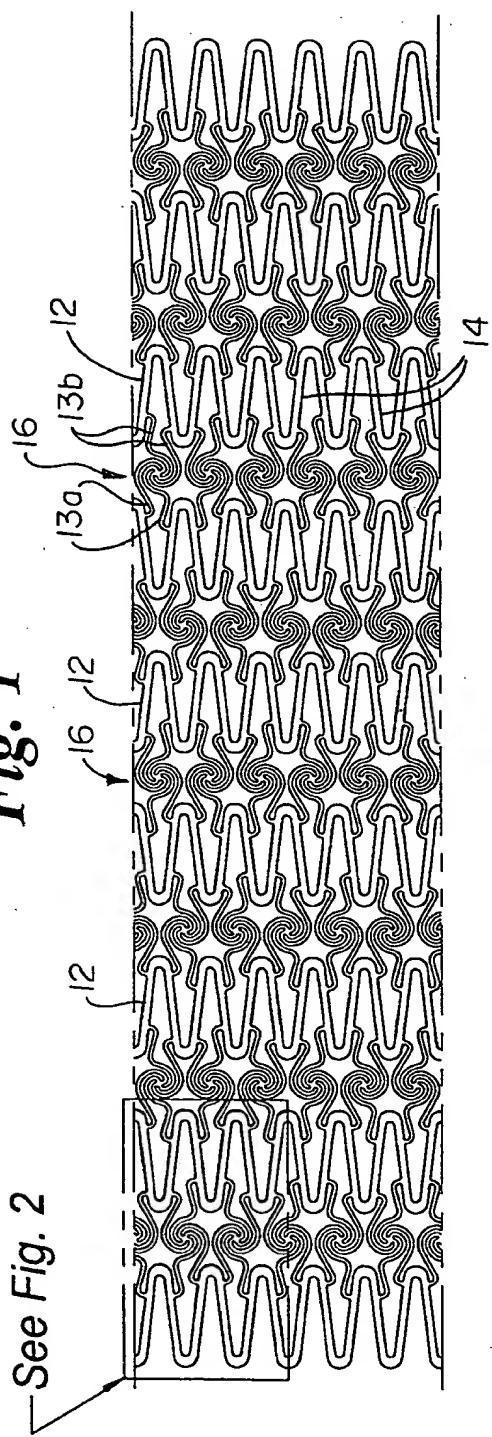
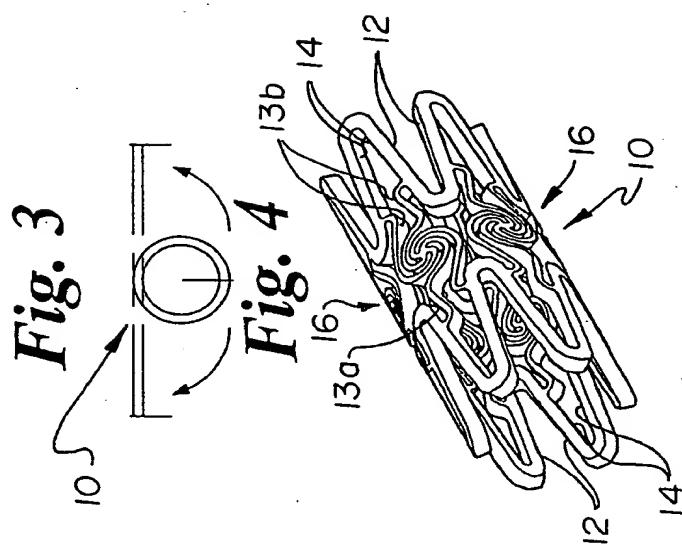
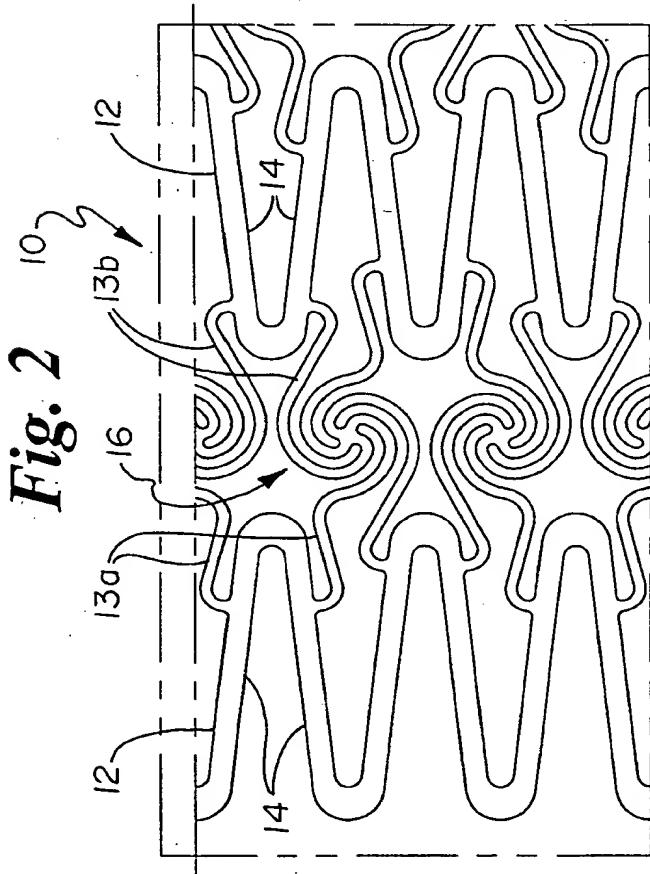
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elements extending from an adjacent segment, the connectors forming at least one spiral configuration between the segments, the spirals straightening upon stent expansion.

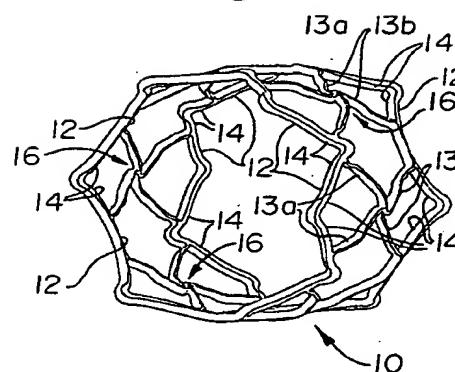
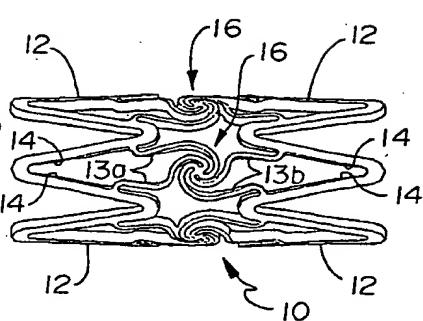
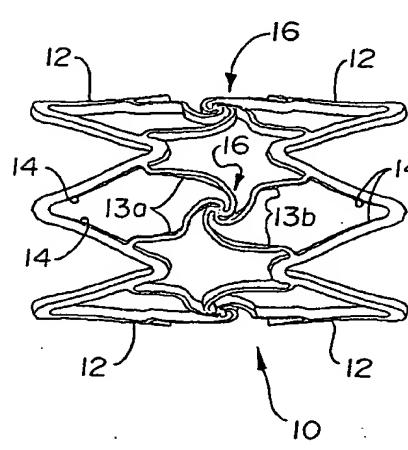
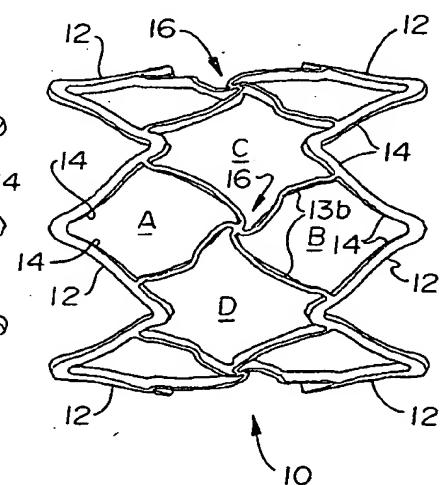
19. The stent of claim 18 wherein the connectors form a plurality of spiral configurations between the segments.

20. The stent of claim 18 wherein the straightening involves unwinding of the spirals.

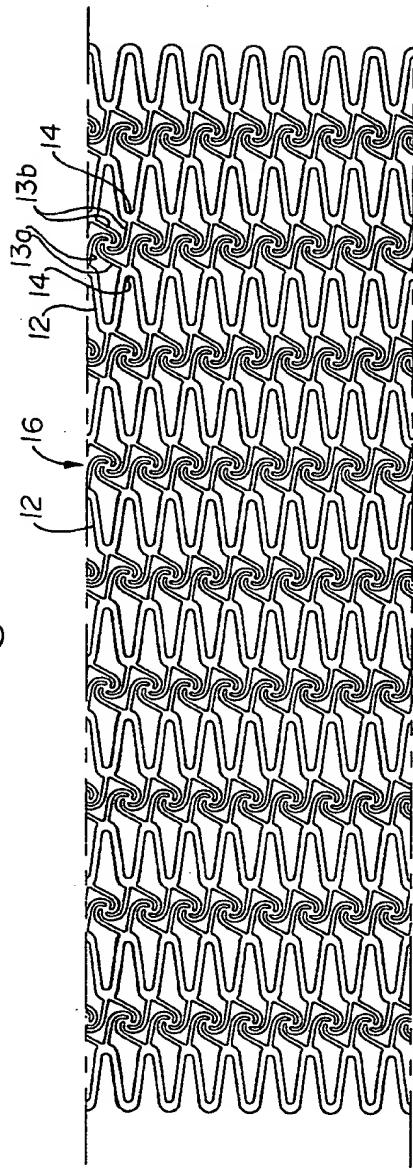
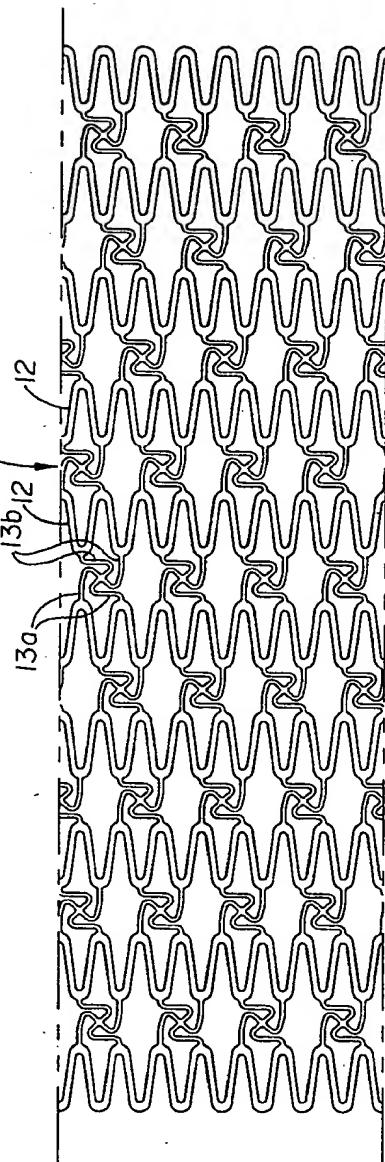
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Fig. 1**Fig. 3****Fig. 4**

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Fig. 5*Fig. 6**Fig. 7**Fig. 8*

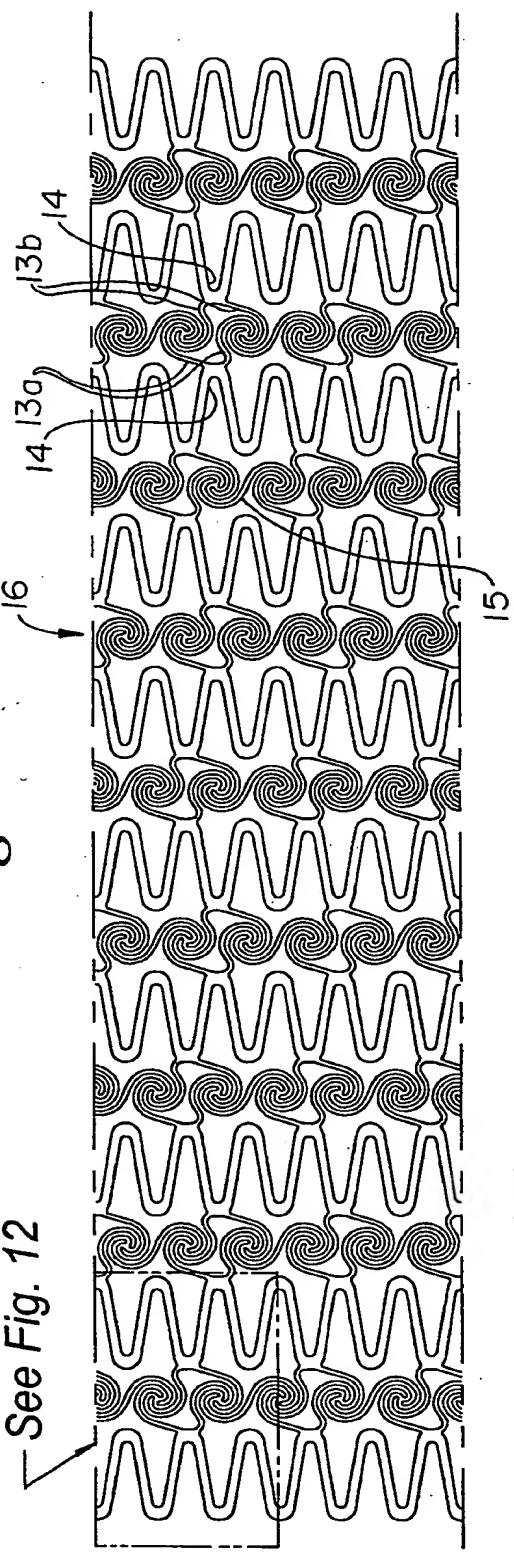
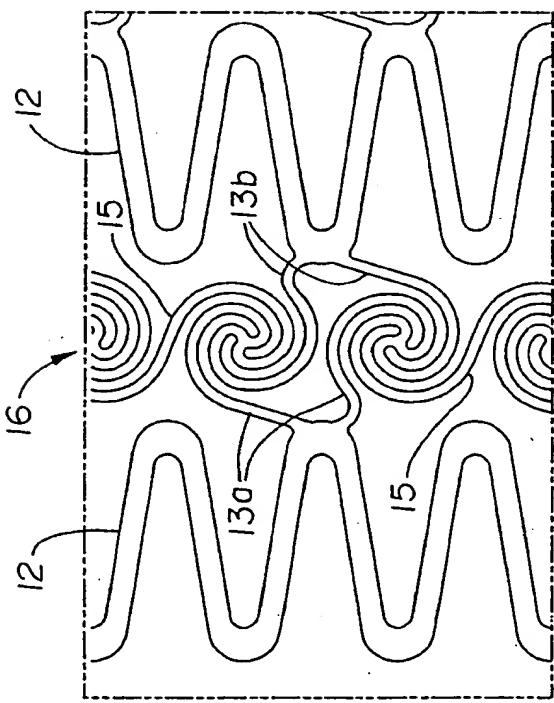
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Fig. 9**Fig. 10**

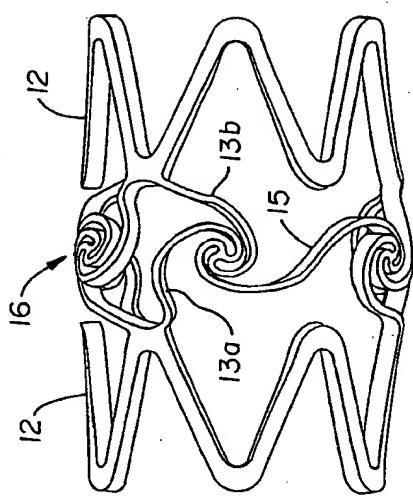
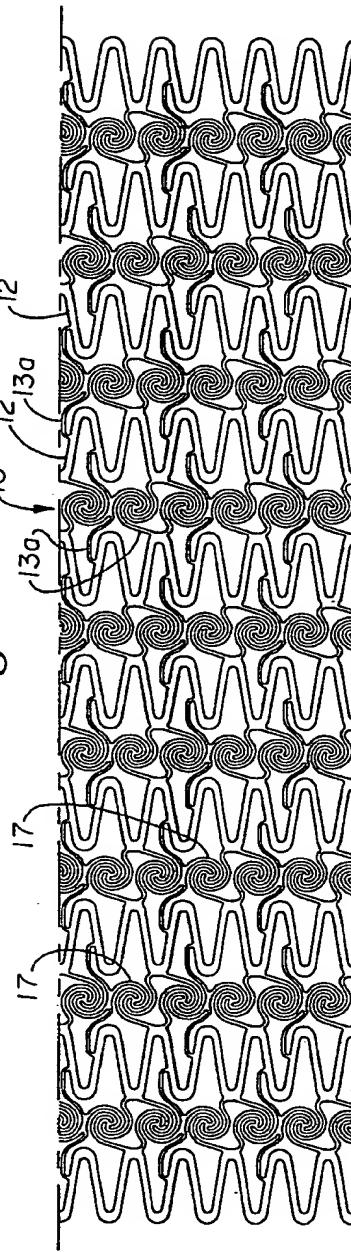
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Fig. 11

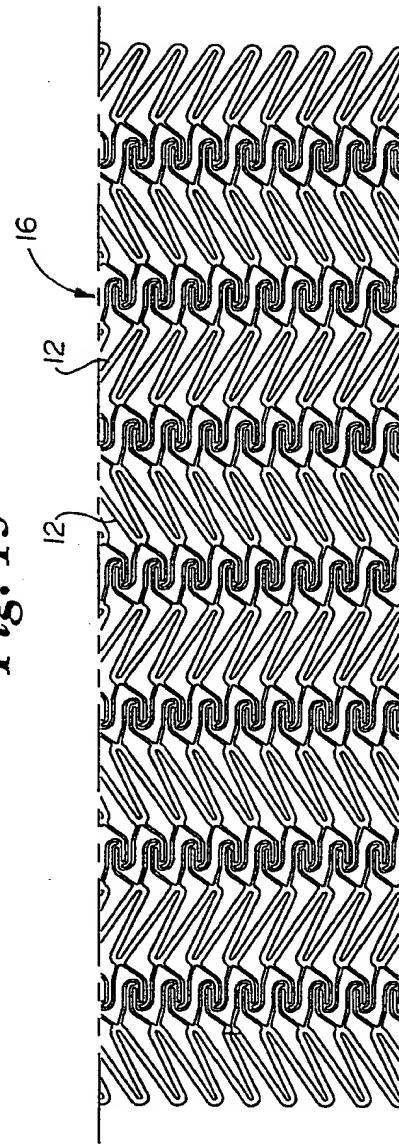
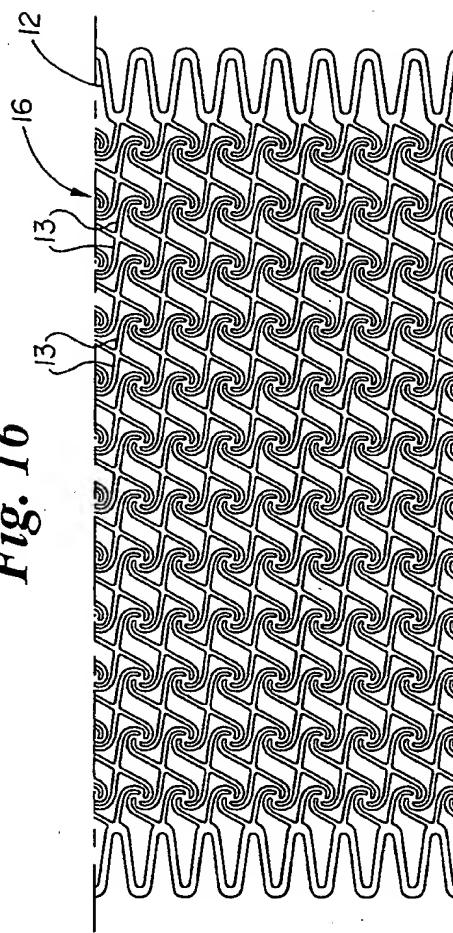
See Fig. 12

**Fig. 12**

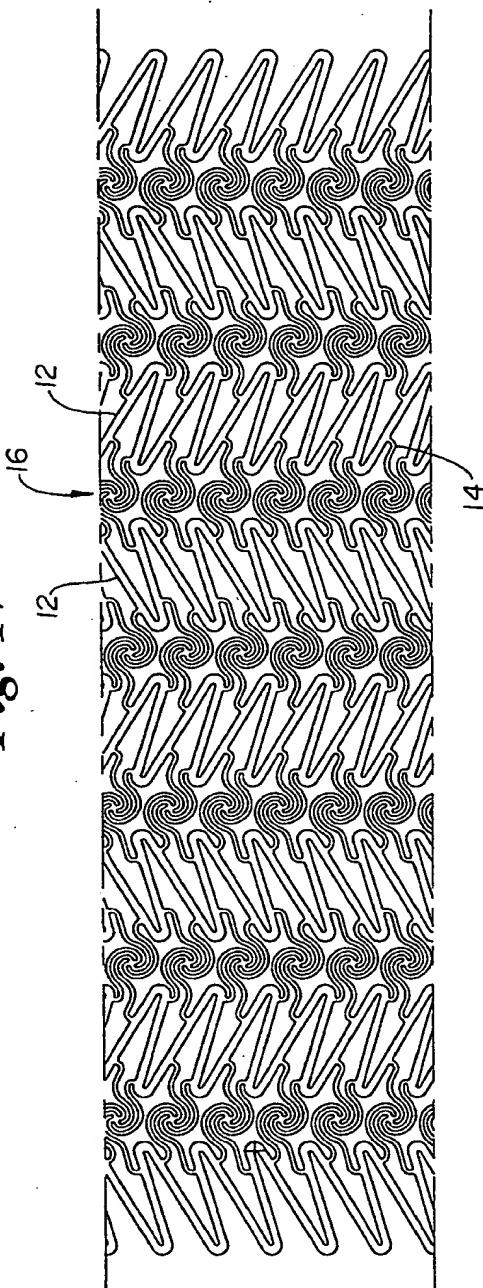
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Fig. 13*Fig. 14*

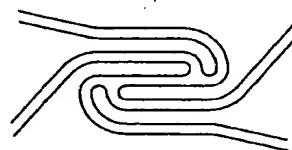
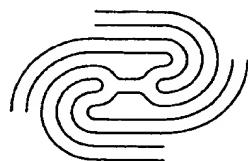
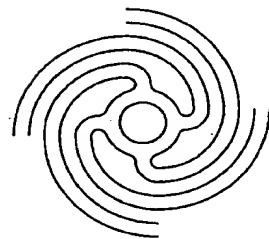
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Fig. 15*Fig. 16*

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Fig. 17

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Fig. 18*Fig. 19**Fig. 20**Fig. 21**Fig. 22**Fig. 23**Fig. 24**Fig. 25*

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Fig. 26

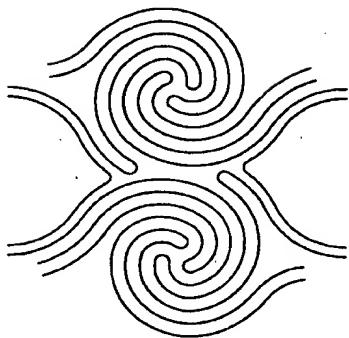


Fig. 27

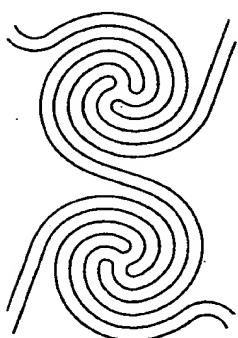
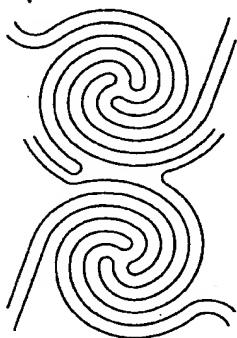


Fig. 28



INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 98/08275

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61F2/06

According to International Patent Classification(IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 421 729 A (MEDTRONIC) 10 April 1991 see figure 3 see page 4, column 5, line 3 - line 13 ---	1,5
X	EP 0 722 700 A (MEDICORPS SA) 24 July 1996 see figures 1,2 see page 3, column 3, line 39 - column 4, line 20 ---	1,3,5
A	DE 297 02 671 U (JOMED IMPLANTATE GMBH) 10 April 1997 see figures 3-10 see page 7, line 13 - line 32 see claims 7,12 ---	1-20 -/-

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Date of mailing of the international search report

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INTERNATIONAL SEARCH REPORT

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Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 549 663 A (COTTONE JR ROBERT J) 27 August 1996 see figure 4 see column 4, line 23 - column 5, line 14 ---	8
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